REMARKS

Applicants submit this Amendment in reply to the Office Action dated June 28, 2005. By this Amendment, Applicants have amended the specification to correct a minor inconsistency in the specification. In particular, amendments have been made to the specification on page 54 correcting a typographical error in order to provide consistent reference to "cannula 316."

In addition, Applicants hereby amend claims 80 and 90 to more clearly define the claimed invention. Before entry of this Amendment, claims 80-99 were pending in this application, with claims 84, 85, and 93 having been withdrawn from further consideration be the Examiner. After entry of this Amendment, claims 80-99 remain pending. The originally-filed specification, claims, abstract, and drawings fully support the subject matter of the amended claims. Exemplary support for the amendment to claim 80 is provided at least in Figures 42A-42C and in the originally filed specification at page 54, lines 18-20; page 55, lines 10-22; and page 56, lines 17-22. No new matter is introduced.

Claim Rejections - 35 U.S.C. § 112

In the June 28, 2005 Office Action, the Examiner rejected claim 90 under 35 U.S.C. § 112, as allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regard as their invention. By this amendment, Applicants have amended claim 90 to recite that "the connector is configured for attachment to a syringe." Accordingly, Applicants submit that the previous rejection under 35 U.S.C. § 112 has been rendered moot.

Claim Rejections - 35 U.S.C. § 102

In the June 28, 2005 Office Action, the Examiner rejected claims 80-83, 86-92, and 94-99 and being anticipated by U.S. Patent No. 6,193,692 to Harris et al. ("Harris"). Applicants respectfully traverse this rejection for the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (8th ed. 2001), p. 2100-70, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Independent claim 80, as amended, recites, *inter alia*, an entry needle comprising a first assembly including a housing, a stylet extending into the housing and a hub in connection with the stylet and adjacent the housing at a proximal end of the entry needle. A second assembly of the needle comprises a cannula surrounding the stylet. The first assembly and the second assembly seal together and are separable, and body fluid cannot pass through the needle when the first and second assemblies are sealed together.

In rejecting independent 80, the Examiner points to item 32 in FIG. 6 of Harris as corresponding to the claimed stylet. (See June 28, 2005 Office Action, Page 2.) In addition, the Examiner also points to FIG. 10 of Harris as disclosing "a blunt stylet." (June 28, 2005 Office Action, Page 3.) Harris, however, does not disclose or suggest at least the claimed features of first and second assemblies that seal together and are separable, and wherein body fluid cannot pass through the needle when the first and second assemblies are sealed together.

The Harris device instead requires that gas or fluid flows through outer sheath member 12 and stylet subassembly 32 for the purpose of insufflating a body cavity. (See, e.g., Harris at column 3, lines 43-52 and Figures 2-7.) The Harris devices provide

for fluid flow therethrough when stylet subassembly 32 and sheath 12 are connected. For example, Harris presents explicit requirements for the flow rate through element 32. In column 4, lines 19-31, Harris recites:

> a projecting hose coupling rib 38 is located to the rear of the valve 36 so that a hose connected to a source of gas, at a pressure greater than ambient or atmospheric, can be attached to the stylet subassembly 30. The inner projection 32 on stylet subassembly 30 is a hollow tube with an opening adjacent the exposed end. This hollow tube 32 fits within the outer sheath 12. The inner diameter of the hollow tube or inner projection 32 is less than the inner diameter of the tubular outer sheath 12. Therefore, the flow rate through the hollow tube 32 is less than the rate of flow that could be achieved through the outer sheath 12 alone.

The currently claimed invention, by contrast, recites that body fluid cannot pass through the needle when the first and second assemblies are sealed together. For example, fluid does not pass through the entry needle as the device is inserted through tissue. As explained in the specification at page 56, lines 17-22, this arrangement allows for needle access within a desired location without requiring the ejection of body fluids to confirm successful placement.

Accordingly, Harris does not teach or suggest the recitations of independent claim 80. For at least the reasons presented above, Applicants respectfully request that the rejection of independent claim 80 and its dependent claims 81-83, 86-92, and 94-99 be withdrawn.

CONCLUSION

In view of the foregoing remarks, this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application.

Applicants therefore respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: September 23, 2005

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